UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' OPPOSITION TO TPP TRIAL DEFENDANTS' OMNIBUS STATEMENT OF MATERIAL FACTS NOT IN DISPUTE

1. Admitted.

2. Admitted in part and denied in part, as the statement does not fully describe all of the bases for Plaintiffs' claims, does not reference Plaintiffs' claims regarding NDEA contaminated API or VCDs, and Plaintiffs claims are not limited to recalled VCDs, but all NDMA and NDEA contaminated API and VCDs. (ECF 1708, ¶ 4-6, 79, 218, 223, 229, 267, 290, 300, 374-402, 404, 421, 614, 631). Further denied that the recalls were voluntary. [redacted]

[1] Teva Exhibits 1 through 86 are attached to the Certification of David J. Stanoch in Support of Plaintiffs' Motion for Partial Summary Judgment. Teva Exhibits 87 through 120 are attached to the Certification of David J. Stanoch in Support of Plaintiffs' Opposition to Defendants' Motion for Summary Judgment.

[redacted] Similarly, ZHP attempted to avoid a recall. (PRINSTON00000041-42 ([redacted].[2]

3. Admitted in part, that ZHP manufactured the at-issue API, denied as to the characterizations of ZHP's wholly owned subsidiaries and the relationship between the entities, and as to the statement that Prinston or Solco manufactured the finished dose VCDs, which were manufactured and labeled by ZHP at its Xunqiao manufacturing facility, and then marketed and distributed via Prinston and Solco. (PRINSTON00000012 (ZHP Ex. 63)). To be clear, ZHP did in fact put the label on the individual bottles in China, and [redacted]

[2] ZHP Exhibits 1 through 125 are attached to the Certification of Adam M. Slater in Support of Plaintiffs' Motion for Partial Summary Judgment. ZHP Exhibits 126 through 168 are attached to the Certification of Adam M. Slater in Support of Plaintiffs' Opposition to Defendants' Motion for Summary Judgment.

[redacted] (PRINSTON00463676, p. 13-14 (ZHP Ex. 146); PRINSTON00463638, p. 13-14 (ZHP Ex. 147); ZHP01890025, p. 13-14 (ZHP Ex. 148); ZHP01890037-38 (emphasis added). [redacted] (PRINSTON00019546 (ZHP Ex. 149); PRINSTONO0177054 (ZHP Ex. 150)). [redacted] (ZHP02457859, 867, 884, 984, 986 (ZHP Ex. 151)). ZHP's, Huahai's,[3] Prinston's, and Solco's logos are also on Solco's "Product List," a document that they have repeatedly withheld "by agreement with counsel," but was available online earlier. (ZHP Ex. 152). This all contradicts ZHP's claim that it was not involved in the "marketing" of the FD VCDs. Additionally, and also contrary to its claims, ZHP sold the FD VCDs to Prinston. (PRINSTON00345256 (ZHP Ex. 153); SOLCO00223261 (ZHP Ex. 154)). ZHP has produced numerous documents showing that Mr. Chen, its CEO, micromanaged the price for its Valsartan API, and efforts to obtain market share, even at the level of its U.S. subsidiaries. (SOLCO00012089 (stating that [redacted]

[3] ZHP and Huahai us the same logo. (*Compare* PRINSTON00012473 (ZHP Ex. 157), *with* PRINSTON00075797 (ZHP Ex. 10)).

[redacted]!" (emphasis added)) (ZHP Ex. 158);[4] SOLCO00189499 ([redacted] (sic)) (ZHP Ex. 159); SOLCO00025179 (ZHP Ex. 160); SOLCO00033301 (ZHP Ex. 161); SOLCO00181380 (ZHP Ex. 162); SOLCO00180393 (ZHP Ex. 163)).

4. Admitted in part and denied in part. [redacted] *See, e.g.*, TEVA-MDL2875-00116005 (Teva-92); TEVA-MDL2875-00020376 (Teva-93); TEVA-MDL2875-00132080 (Teva-94); TEVA-MDL2875-00489580 (Teva-95); TEVA-MDL2875-00155644 (Teva-96).

[4] This document shows Mr. Chen decided what market share to target for valsartan at ZHP and even its U.S. subsidiaries, and only Mr. Chen knows how he established the targets.

[redacted]. *See, e.g.*, TEVA-MDL2875-00049024 (Teva-118).

5. Admitted.

6. Admitted that the Drug Master File was submitted on or about the date stated, and provided information about the manufacturing process but denied that the process was "proposed," as that term is undefined and the TIN process followed the branded process. (ZHP01661566, at 569-574 (Defs.' Ex. 11)).

7. Admitted in part, but unable to admit or deny as to whether the DMF is "active" as that term is not defined, and denied that ZHP's expert report is a legitimate or correct source of facts for the statement of undisputed material facts.[5]

[5] Plaintiffs object to Defendants' citations to expert reports and expert deposition testimony as a source of facts to be relied on in their statement of undisputed material facts. *In re Citric Acid Litig.*, 191 F.3d 1090, 1102 (9th Cir. 1999) (holding that "an expert report cannot be used to prove the existence of facts set forth therein."); *see also Doe v. City of San Diego*, 35 F.Supp.3d 1233, 1236-37 (S.D. Cal. 2014) (holding that the "[p]laintiff has improperly supported her statement of facts by citing to the factual statements set forth by her expert witnesses in their reports rather than citing to facts in the record"); *Kaur v. City of Lodi*, 263 F. Supp. 3d 947, 977 (E.D. Cal. 2017) (holding: "Consequently, where the City Defendants cite expert declarants, who have no personal knowledge of the events relevant to the encounter between Parminder and the Officer Defendants, for the proposition that these facts occurred, they are improperly supported."); *Hyer v. City & Cnty. of Honolulu*, 654 F. Supp. 3d 1111, 1138 (D. Haw. 2023) (noting: "Plaintiffs may not use an expert report to prove the existence of facts.");*Grimes v. D.C.*, 308 F. Supp. 3d 93, 108 (D.D.C. 2018) (same). This objection is incorporated by reference in the responses to all statements of Defendants' statements of undisputed material facts that rely on an expert report and/or expert deposit4ion testimony as a source of the stated facts.

8. Admitted that the Drug Master File was submitted on or about the date stated, and was designated as a USP compliant process, and that triethylamine hydrochloride was substituted for the tributyl tin chloride, denied as to the characterization of ZHP's decision to "move away" from the TIN process as that term is ambiguous and does not state ZHP's prevailing interest in lowering cost and increasing yield (PRINSTON00162373 (ZHP Ex. 13)), denied as to the statement that this DMF is "active" today as that term is not defined and is ambiguous, and [redacted]. PRINSTON00000042-46 ([redacted]) (ZHP Ex. 61).

9. Admitted that the Amendment was filed on or about April 16, 2012, and admitted that the quoted statements were made, [redacted]. (Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (ZHP Ex. 46) (discussing ZHP Ex. 122)).

10. Admitted that ZHP performed a test or tests regarding the TEA processes, however cannot admit or deny as to the timing of the unnamed and unlisted tests which is ambiguous, and denied as to the efficacy or adequacy of the testing, which led to the stated incorrect conclusion that there would be no negative effects on product quality, where undisclosed genotoxic nitrosamine impurities were formed to contaminate the product. (PRINSTON00075797, 75803-76037 (ZHP Ex. 10)).

11. Admitted that the TEA without quenching and TEA with quenching processes were developed by ZHP, however cannot admit or deny as to the timing of the actions stated as no dates and inadequate specificity is/are stated.

12. Admitted that ZHP developed the zinc chloride process with the stated changes to the manufacturing process, and filed a DMF amendment, but denied that the description in the statement is complete, [redacted], and denied as to the statement that DMF was a "common solvent" which is an undefined term. (ZHP01843066, ZHP 195 (ZHP Ex. 12)).

13. Admitted that ZHP made the listed statements, denied that the statements were all correct, for example failing to state that the reasons for the development of the process included reducing cost and increasing yield to increase

market share. (PRINSTON00162373 (ZHP Ex. 13); ZHP01843067, 1843099, 1843116 (ZHP Ex. 12)).

14. Denied. The primary purpose was to reduce cost and increase yield to increase market share. (PRINSTON00162373 (ZHP Ex. 13); ZHP01843067, 1843099, 1843116 (ZHP Ex. 12)).

15. Admitted as to sources of current good manufacturing practices, but denied that the list of sources is a complete list, e.g. 2008 FDA Guidance titled "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches" . ((ZHP Ex. 143); Eric Gu 4/5/21 Dep. Tr., 69:1-70:23 (ZHP Ex. 31)).

16. Denied, as the 2017 inspection identified numerous violations (PRINSTON00085364-374 (ZHP Ex. 168)), ZHP failed to disclose material information to the FDA that would have led to the discovery of numerous unidentified violations for example the failure to conduct scientifically adequate risk assessments (PRINSTON00075807-76037 (ZHP Ex. 10); ZHP00004365-4396 (ZHP Ex. 14)), and the reference to "predominantly compliant findings" is denied as it is ambiguous and undefined and ignores the fact that the at-issue manufacturing processes created undisclosed, unacceptable and unapproved genotoxic human carcinogens. (*Id.*).

17. Admitted that ZHP was served with a Warning Letter, denied that ZHP voluntarily reported the NDMA contamination that was reported in June 2018 [redacted] (ZHP00310309-10 (ZHP Ex. 126); ZHP00380568 (ZHP Ex. 127); ZHP01390017 (ZHP Ex. 128); ZHP02214647 (ZHP Ex. 129); ZHP00359796 (ZHP Ex. 130); ZHP00405021 (ZHP Ex. 44)), [redacted] (PRINSTON00000041-42 (s[redacted]) (ZHP Ex. 61); *see also* PRINSTON00000001 (ZHP Ex. 80).; PRINSTON00000005 (ZHP Ex. 82); PRINSTON00000011 (ZHP Ex. 63); PRINSTON00000019 (ZHP Ex. 61); ZHP01344159 (ZHP Ex. 28)), and denied that the timeline of events from the issuance of the Warning Letter to the lifting of the Import Ban is complete. (PRINSTON00074174 (ZHP Ex. 131); ZHP01447094 (ZHP Ex. 132); ZHP01429887 (ZHP Ex. 133); PRINSTON00147028 (ZHP Ex. 134)).

18. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. (See Footnote 6). [redacted]. *See, e.g.*, TEVA-MDL2875-0015725 (Teva-97) (discussing FDA Form 483 from April 2014).

[redacted] *See, e.g.*,

See, e.g., Gray Dep. at 154:21-156:10 (Teva-111); TEVA-MDL2875-00346079 (Teva-98). [redacted]

19. Denied. *See infra* ¶ 18; *see also* Teva SOMF ¶¶ 78-95.

20. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. (See Footnote 6). [redacted]

21. Denied. *See infra* ¶ 20.

22. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. (See Footnote 6). [redacted] *See* Teva SOMF ¶¶ 42-55.

23. Denied that Plaintiff's expert, Philip Russ, identified Teva Defendants' Annual Product Reviews as some of the "best" testing records available. To the

contrary, Mr. Russ testified that [redacted]

24. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. Otherwise denied [redacted]

[redacted]

25. Admitted that in the years leading up to the recall of valsartan-containing drugs, Torrent's Indrad facility was inspected by the FDA. Deny that Torrent "passed" inspections or that "pass" was even a potential result of an FDA inspection.[6] [redacted]

[6] *See* FDA, FDA Inspections Database Frequently Asked Questions, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-data base-frequently-asked-questions (last accessed Jan. 4, 2024).
[7] *Id.*

26. Admit that Torrent tested the API it received from ZHP. Deny that Torrent tested the API for nitrosamines prior to the recall. (*See*, *e.g.*, Torrent SOMF ¶ 10, 12, 20, 41–42, 50. Nigh Cert. Ex. 2, at 284:3–285:20, 286:7–12.) [redacted]

27. Admit that Torrent had *a* procedure to qualify ZHP as an API supplier. Denied that this procedure is appropriately characterized as a "robust supplier qualification program," which is an undefined term. Plaintiffs further object to reliance on expert opinions as the basis for statements of undisputed material facts. (See Footnote 6).[8] [redacted]

[8] With respect to Dr. Nagaich's opinions about Torrent's purported compliance with cGMP requirements (the sole basis for this statement), the Court concluded that it was "completely unclear whether the reviewed documents were cherry-picked to highlight Torrent's compliance" such that the Court could not determine "how much of his opinions is *ipse dixit*." (ECF 2581, at 14.)

[redacted] (Nigh Cert., Ex. 3, at 117:15–118:11, Ex. 6, at 183:3–184:10.)

28. Denied as this is a legal conclusion.

29. Admit that the Warning Letter issued by the FDA in October 2019,[9] did not explicitly reference API *testing* though it did reference out of specification results for API. Deny that the Warning Letter did not pertain to impurities. The letter specifically referenced the recall of Torrent's product for "unacceptable amounts of nitrosamine impurities."[10] However, admit that the amount of impurities at issue were not "trace" amounts of impurities but rather were "unacceptable" amounts of impurities, as stated by the FDA.

30. Admit that Torrent relied on third-party auditors. Otherwise, denied as this is a legal conclusion.[11]

31. Admit that Torrent performed some testing on its VCDs. Deny that this testing was adequate, in accordance with compendial requirements, approved regulatory specifications, and industry standards. [redacted]

[9] *See* Warning Letter, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019 (last accessed Jan. 4, 2019).

[10] *Id.*

[11] With respect to Dr. Nagaich's opinions about Torrent's purported compliance with cGMP requirements (the sole basis for this statement), the Court concluded that it was "completely unclear whether the reviewed documents were cherry-picked to highlight Torrent's compliance" such that the Court could not determine "how much of his opinions is *ipse dixit*." (ECF 2581, at 14.)

[redacted]

(Torrent SOMF ¶ 51–56.)[12]

32. Admit that Dawn Chitty testified [redacted]

(Nigh Cert., Ex 3, at 229:9–16; *see also* Nigh Suppl. Cert. Exs. 30–33, 35–36.)

33. Admit that Torrent's corporate representative stated [redacted]

(*Id.* at 258:12–24.)

[12] Plaintiffs further object to the reliance on expert reports for statements of undisputed material facts, particularly where excluded as legal opinions. (*See* ECF 2581, at 15.)

34. Admitted that Novartis notified ZHP of its findings of unknown peaks and that emails were exchanged. Denied that the two companies "worked together" since Novartis identified the NDMA, and ZHP was primarily deflecting the inquiry as it had prior complaints and inquiries from a series of customers going back years. (ZHP00405021 (ZHP Ex. 44); ZHP00359796 (ZHP Ex. 130); ZHP02214647 (ZHP Ex. 129); ZHP01390017 (ZHP Ex. 128); ZHP00380568 (ZHP Ex. 127); ZHP00310309 (ZHP Ex. 126); ZHP01870977 (ZHP Ex. 135); ZHP00021455 (ZHP Ex. 136); Qiangming Li 4/14/2021 Dep. Tr. 130:7-170:11 (ZHP Ex. 32); ZHP01748896, ZHP 260 (ZHP Ex. 33); Qiangming Li 4/14/2021 Dep. Tr. 177:22-199:20; ZHP01748905, ZHP 264 (ZHP Ex. 34); Qiangming Li 4/15/2021 Dep. Tr. 290:16-318:10 (ZHP Ex. 24); ZHP00405069, ZHP 277 (ZHP Ex. 36); ZHP01313866, ZHP 278 (ZHP Ex. 37); Qiangming Li 4/14/2021 Dep. Tr. 204:11-214:17; ZHP02630924, ZHP 265 (ZHP Ex. 38); ZHP02630926, ZHP 266 (ZHP Ex. 39); Qiangming Li 4/15/2021 Dep. Tr. 254:22-290:4; ZHP00496153, ZHP 271 (ZHP Ex. 40); ZHP00496155, ZHP 272 (ZHP Ex. 41); ZHP02118712, ZHP 273 (ZHP Ex. 42); Qiangming Li 4/15/2021 Dep. Tr. 343:21-372:9; ZHP02094739, ZHP 281 (ZHP Ex. 43); Qiangming Li 4/15/2021 Dep. Tr. 386:17-466:17; ZHP00405021, ZHP 284 (ZHP Ex. 44)).

35. Denied that Novartis "suggested" the use of Solvias, rather [redacted]

[redacted]. (ZHP00359796-359800 (ZHP Ex. 130)). Admitted that Novartis and Solvias identified the NDMA.

36. Denied that ZHP acted "immediately," [redacted]. (PRINSTON00000001 (ZHP Ex. 80)).

37. Denied that ZHP and Prinston "worked closely" with the FDA, [redacted]. (*Id.*; PRINSTON00000005 (ZHP Ex. 82); PRINSTON00000011 (ZHP Ex. 63); PRINSTON00000019 (ZHP Ex. 61); ZHP01344159 (ZHP Ex. 28)).

38. Denied that this occurred "shortly" after confirmation of the NDMA, which was known at least as of July 27, 2017, and did not occur "shortly" after confirmation in June, 2018, [redacted]. (Min Li 4/20/2021 Dep. 82:11-12, 87:19-88:7, 88:13-89:18 (ZHP Ex. 11) (discussing ZHP-

295 (ZHP Ex. 109)); ZHP's Trans. of ZHP00190573 (ZHP Ex. 24); Pls.' Trans. of ZHP00190573 (ZHP Ex. 108)).

39. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. (See Footnote 6). Otherwise denied as stated. [redacted]

[redacted]

40. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. (See Footnote 6). [redacted] *See, e.g.*, Binsol Dep. at 127:4-128:12, 137:13 – 138:109 (Teva-113); Anderson Dep. at 38:11-14 & 141:7-143:9 (Teva-117); Williams Dep. at 232:5-233:11 (Teva-118).

41. Denied. Defendants' only citation is to their own expert testimony, which is insufficient to establish a material fact. (See Footnote 6). [redacted]

42. Deny that Torrent first learned of the nitrosamine impurity in ZHP's API on June 20, 2018, that the impurity was limited to NDMA, or that it was unclear

whether all valsartan API was affected. [redacted] (*See* Torrent SOMF ¶ 24, 24(a), 24(b), 50, 50(a); Nigh Cert. Ex. 3, at 117:15–118:111, 183:3–184:10; Nigh Suppl. Cert. Exs. 29, 31.) Admit that ZHP sent a notification to Torrent on June 20, 2018, pertaining to a genotoxic impurity in the API. Admit that Torrent temporarily quarantined the product.

43. Deny that the specifics of the manufacturing process led or would leave ZHP to believe the valsartan API supplied to Torrent did not contain the nitrosamine impurity. (*See* Torrent SOMF ¶ 50, 50(a).) Admit that ZHP made statements that falsely represented that the valsartan API ZHP provided to Torrent manufactured using the TEA process did not contain nitrosamine impurities and that only valsartan API manufactured with the Zinc Chloride process contained nitrosamine impurities. (Nigh Suppl. Cert. Exs. 29, 31.). Deny that the information ZHP provided to Torrent indicated that the ZHP API used by Torrent in manufacturing VCDs was not affected by the nitrosamine impurity. (*See* Torrent SOMF ¶ 50, 50(a).)

44. Admit that on June 26, 2018, Torrent received a notice from ZHP stating that the genotoxic impurity only affected D code valsartan API; deny that this "confirmed" batches manufactured using the TEA process were not affected. [redacted] (*See* Torrent SOMF ¶ 24, 24(a), 24(b).)

45. Admit that August 3, 2018 was the first time ZHP explicitly notified Torrent that C code valsartan API manufactured with the TEA process contained NDMA. Deny that the amount of NDMA is appropriately characterized as a "trace" amount or that Torrent had no reason to believe there were nitrosamine impurities in the API prior to receiving this notification. (*See* SOMF ¶ 50, 50(a), 50(b); (Nigh Cert. Ex. 1, at 334:12–23; Ex. 2, at 449:13–18, 468:7–9; Ex. 3, at 117:15–118:11; Ex. 6 at 183:8–184:10.) [redacted]. (Nigh Cert. Ex. 2, at 449:13–18, 474:4–10, 476:1–2.)

46. Admitted.

47. Denied that this occurred "immediately," [redacted]. (ZHP00009256, 9263 (Defs.' Ex. 56)).

48. Admitted that this testing occurred on or about the stated date, denied as to the characterization of "trace" amounts, which suggests that the amounts were insignificant, which is untrue. (TORRENT-MDL2875-00074133 (ZHP Ex. 137)).

49. Admitted that these statements were made in the FDA statement.

50. Admitted that the DIRs summarize ZHP findings, denied as to the characterization of the DIRs as preliminary and final, they are not characterized in

that manner in the actual documents. (ZHP00004393-4396 (ZHP Ex. 14); PRINSTON00076022-76037 (ZHP Ex. 10); PRINSTONO0076119 (ZHP Ex. 120)).

51. Admitted that these statements are found in the cited DIR, denied as to the characterization of that DIR as final (See response to ¶ 50).

52. Admitted that these statements are found in the cited DIR, denied as to the characterization of that DIR as final (See response to 50), and denied that this is a complete statement of the findings as to the root cause, as the DIR documents the finding that TEA can nitrosate directly. (PRINSTON00761002-03 (ZHP Ex. 120)).

53. Plaintiffs object to reliance on expert opinions as the basis for statements of undisputed material facts (See Footnote 6), and deny that the cited statements are a complete picture of Dr. Najafi's opinions on this subject. (*See* Footnote 6).

54. Admitted that these issues were investigated, but denied that this statement is a complete statement as to the scope of ZHP's investigation, for example failing to reference the findings documented on July 27, 2017, and the finding in one of the DIR's that TEA can nitrosate directly (Min Li 4/20/2021 Dep. 82:11-12, 87:19-88:7, 88:13-89:18 (ZHP Ex. 11) (discussing ZHP-295 (ZHP Ex. 109)); ZHP's Trans. of ZHP00190573 (ZHP Ex. 24); Pls.' Trans. of ZHP00190573 (ZHP Ex. 108); PRINSTON00761002-03 (ZHP Ex. 120)). The language of this email is

unequivocal, and Min Li's testimony that [redacted] is both absurd and unavailing. (Min Li 4/21/21 Dep. Tr., 434:17-435:5 (ZHP Ex. 33)).

55. Admitted that this root cause was confirmed by ZHP, but denied that this was the only root cause identified, for example failing to reference the finding that TEA can nitrosate directly (PRINSTON00761002-03 (ZHP Ex. 120)).

56. Admitted that this finding was documented by ZHP, but denied that this is the only finding by ZHP, which also found that DMA could be introduced as an impurity of DMF as purchased. (PRINSTONO0075947 (ZHP Ex. 10); ZHP00004369 (ZHP Ex. 14)).

57. Denied as to characterization of the described publications as "limited" as that term is not defined and there is no factual basis offered for that description. Moreover, this case is not about what an average chemist knows. It is about what ZHP's professional pharmaceutical chemists should have known when developing a new manufacturing process for valsartan. (Dr. Hecht 1/13/23 Dep. Tr., 79:6-11 (ZHP Ex. 138)). Furthermore, DMF does not have to reach its boiling point to decompose into DMA. Dr. Najafi testified, "[I]t will also degrade at [redacted] degrees Celsius." (Dr. Najafi 1/18/2023 Dep. Tr., 207:2-3 (ZHP Ex. 164)). Dr. Hecht agreed, also referencing formation via hydrolysis: "I can tell you from experience that it -- you're going to get some dimethylamine, if you heat DMF at [redacted] degrees for [redacted]

hours," as ZHP did in the ZnCl2 process. (Dr. Hecht 1/13/23 Dep. Tr., 219:3-6, 296:6-8, 94:6-95:12 (ZHP Ex. 138)).

58. Plaintiffs object to reliance on expert opinions as the basis for statements of material facts (See Footnote 6), and deny that the described mechanism was posited as necessary for the formation of NDMA in the at-issue manufacturing processes. Admitted that the cited testimony indicates the boiling point was not supposed to be reached, however Dr. Hecht also testified that the conditions of the manufacturing process including the temperatures and length of time for certain steps in the process were clearly adequate for the formation of NDMA. Dr. Hecht confirmed, "When they decided to use nitrite in the reaction mixture, they should have thought about nitrosamine formation," and "[T]here's no doubt that DMF can hydrolyze to dimethylamine when you heat it for [redacted] hours at [redacted] degrees, or whatever it was…." (Dr. Hecht 1/13/23 Dep. Tr., 296:6-8, 94:6-95:12 (ZHP Ex. 138); *see also id.* at 219:3-6. Furthermore, Dr. Najafi testified that DMF "will also degrade at [redacted]degrees Celsius." (Dr. Najafi 1/18/2023 Dep. Tr., 207:2-3 (ZHP Ex. 164)).

59. Plaintiffs object to the series of compound statements listing expert opinions as opposed to factual statements of record. (See Footnote 6). As already noted, Dr. Hecht was clear that he was opining as to what ZHP's professional pharmaceutical chemists should have known when developing a new manufacturing

process for valsartan, not the knowledge of the average chemist. (Dr. Hecht 1/13/23 Dep. Tr., 79:6-11 (ZHP Ex. 138)). Contrary to Defendants' accusation that "Dr. Hecht was unable to identify any scientific literature that documented a reaction between TEA and sodium nitrite leading to the creation of NDEA prior to or during the time that the TEA with quenching process was being used to manufacture ZHP's API," the very first footnote of Dr. Hecht's first report cites to Sun, Z., Liu Y.D., and Zhong, R.G. (2010) *Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine*, J. Phys. Chem. A. 114, 455-465; 29, which is the article ZHP cites in its final DIR for the proposition that TEA can directly nitrosate with nitrous acid, and it predates ZHP's development of the TEA with sodium nitrite quenching manufacturing process. (Dr. Hecht 7/6/2021 R. 27 (ZHP Ex. 139); PRINSTON00076102-03 (ZHP Ex. 120)). Defendants double down on this mischaracterization of Dr. Hecht's report when they write "Dr. Hecht has acknowledged that it was historically understood that "a tertiary amine," such as TEA "would not react" with sodium nitrite to form a nitrosamine," but the report clarifies that this antiquated understanding was "later shown to be not completely correct," as documented, for example, in the Sun study. (Dr. Hecht 7/6/2021 R. 27 (ZHP Ex. 139); PRINSTON00076102-03 (ZHP Ex. 120)). To be clear, Dr. Hecht then wrote, "**Decades of research** and volumes of published material clearly demonstrate that nitrite can react easily with amines to produce carcinogenic

nitrosamines." (Dr. Hecht 7/6/2021 R. 27 (emphasis added) (ZHP Ex. 139)). Contrary to Defendants' assertion that Dr. Najafi testified that he was not aware of the textbook regarding the temperature necessary for DMF to boil until he was retained for this litigation, Dr. Najafi testified that he did not recall when he first became aware of the textbook regarding the temperature necessary for DMF to boil. (Dr. Najafi 1/18/2023 Dep. Tr., 202:24-203:1 (ZHP Ex. 164)). Defendants further misconstrue Dr. Najafi's testimony to make it appear that Dr. Najafi testified that he would not have known that TEA exposed to sodium nitrite could form NDEA had he not been an expert in this litigation. Dr. Najafi actually testified that he immediately suspected sodium nitrite as the culprit, "you know, my thinking was sodium nitrite, that – immediately that jumped at me without doing any research because of the history of sodium nitrite." (*Ids.*, at 193:15-18)).

60. Denied that a "theory" was advanced, and denied that there is no evidence that DEA could be introduced via TEA, as this is recognized in the DIR (PRINSTON00075855 (ZHP Ex. 10)), and in the Certificate of Analysis from the supplier of TEA to ZHP. (PRINSTONO0075957 (ZHP Ex. 10); Zhejiang Jianye Chemical Co., Ltd., Certificate of Analysis for Triethylamine (ZHP Ex. 50)). In addition, [redacted]. (Min Li 4/20/21 Dep. Tr. 77:8-80:16 (ZHP Ex. 11)).

61. Admitted that this was stated by the FDA, however denied that this is a complete statement of the FDA's position, but rather is a misleading cherry picked part of what the FDA has stated, for example the FDA made clear that ZHP violated cGMPs for its failings and pointed out that ZHP was in the best position to know and disclose this, as opposed to the FDA on a routine inspection:

> Since then, the FDA and additional manufacturers of other ARB medicines have identified more cases of NDMA impurities, as well as NDEA impurities. **We've placed a ZHP facility on import alert to stop all its API and finished drugs made using ZHP's API from legally entering the U.S. We also issued them a warning letter outlining several manufacturing violations, including impurity control, change control and cross contamination from one manufacturing process line to another. It's unlikely that the subtle problems causing these impurities could have been found on a routine current good manufacturing practice (CGMP) inspection. Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise**.

FDA, FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues (Jan. 25, 2019) (ZHP Ex. 140) (emphasis added). The FDA's November 29, 2018 Warning Letter was even more clear and specific, cataloging a number of cGMP violations directly tied to the manufacture of the contaminated ZHP valsartan, including:

> **1. Failure of your quality unit to ensure that quality-related complaints are investigated and resolved.**

Valsartan API

Your firm received a complaint from a customer on June 6, 2018, after an unknown peak was detected during residual solvents testing for valsartan API manufactured at your facility. **The unknown peak was identified as the probable human carcinogen N-nitrosodimethylamine (NDMA).** Your investigation (DCe-18001) determined that the presence of NDMA was caused by the convergence of three process-related factors, one factor being the use of the solvent dimethylformamide (DMF). Your investigation concluded that only one valsartan manufacturing process (referred to as the process in your investigation) was impacted by the presence of NDMA. However, FDA analyses of samples of your API, and finished drug product manufactured with your API, identified NDMA in multiple batches manufactured with a different process, namely the triethylamine process, which did not use the solvent DMF. These data demonstrate that your investigation was inadequate and failed to resolve the control and presence of NDMA in valsartan API distributed to customers. Your investigation also failed:

- To include other factors that may have contributed to the presence of NDMA. For example, your investigation lacked a comprehensive evaluation of all raw materials used during manufacturing, including potable water.

- To assess factors that could put your API at risk for NDMA cross-contamination, including batch blending, solvent recovery and re-use, shared production lines, and cleaning procedures.

- To evaluate the potential for other mutagenic impurities to form in your products.

Our investigators also noted other examples of your firm's inadequate investigation of unknown peaks observed in

chromatograms. For example, valsartan intermediates (C20213-17-339 and C20213-17-340) failed testing for an unknown impurity (specification < 0.5%) with results of 0.56% for both batches. Your action plan indicated that the impurity would be identified as part of the investigation; however, you failed to do this. In addition, no root cause was determined for the presence of the unknown impurity. You stated that you reprocessed the batches and released them for further production.

Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. For example, you told our investigators you were aware of a peak that eluted after the toluene peak in valsartan API residual solvent chromatograms where the presence of NDMA was suspected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further. Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your ZnCl2 process, with DMF in 2012 (C5355-12-001, C5355-12-002, and C5355-12-003) show at least one unidentified peak eluting after the toluene peak in the area where the presence of NDMA was suspected to elute.

Your response also states that you were not the only firm to identify NDMA in valsartan API. In your case, FDA analyses of samples identified amounts of NDMA in valsartan API manufactured at your firm that were significantly higher than the NDMA levels in valsartan API manufactured by other firms. FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, and because of the significant inadequacies in your investigation.

* * *

2. Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API.

In November 2011 you approved a valsartan API process change (PCRC - 11025) that included the use of the solvent DMF. **Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine.** According to your ongoing investigation, dimethylamine is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients.

Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce.

> Your response does not describe sufficient corrective actions to ensure that your firm has adequate change management procedures in place: (1) to thoroughly evaluate your API manufacturing processes, including changes to those processes; and (2) to detect any unsafe impurities, including potentially mutagenic impurities. For FDA's current thinking on control of potentially mutagenic impurities, see FDA's guidance document M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk for approaches that FDA considers appropriate for evaluating mutagenic impurities, at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM347725.pdf.

(ZHP01344159 (ZHP Ex. 28)) (emphasis added). The Letter also stated: "Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance," and "You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations." (*Id.* at 5).

62. Admitted that this was stated by the FDA, however denied that this is a complete statement of the FDA's position, but rather is a misleading cherry-picked part of what the FDA has stated. See Paragraph 61 for more details.

63. Admitted that this was stated by the FDA, however denied that this is a complete statement of the FDA's position, but rather is a misleading cherry-picked part of what the FDA has stated. See Paragraph 61 for more details.

64. Admitted that this was stated by the FDA, however denied that this is a complete statement of the FDA's position, but rather is a misleading cherry-picked part of what the FDA has stated. See Paragraph 61 for more details.

65. Admitted that this was stated by the FDA, however denied that this is a complete statement of the FDA's position, but rather is a misleading cherry-picked part of what the FDA has stated. See Paragraph 61 for more details.

66. Plaintiffs object to the series of compound statements listing expert opinions as opposed to factual statements of record. (See Footnote 6). Admitted that Dr. Najafi identified the July 27, 2017 email as demonstrating ZHP's knowledge that there was NDMA in valsartan, and admitted that Dr. Xue offered the stated opinion, which the Court precluded, along with all of his substantive opinions seeking to exonerate ZHP, and denied as to the characterization of what the email states and the import of the email. (ECF 2581, at 18-19; Min Li 4/20/2021 Dep. 82:11-12, 87:19-88:7, 88:13-89:18 (ZHP Ex. 11) (discussing ZHP-295 (ZHP Ex. 109))).

67. Denied. (See Footnote 6). The FDA's Warning Letter stated:

> Your response states that NDMA was difficult to detect. **However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA.** For example, you told our investigators you were aware of a peak that eluted after the toluene peak in valsartan API residual solvent chromatograms where the presence of

> NDMA was suspected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further. Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your ZnCl2 process, with DMF in 2012 (C5355-12-001, C5355-12-002, and C5355-12-003) show at least one unidentified peak eluting after the toluene peak in the area where the presence of NDMA was suspected to elute.
>
> * * *
>
> Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that that your process development study was adequate. We disagree. **We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce.**

(ZHP01344160-61 (ZHP Ex. 28)). **The Defendants agree that the manufacturer is responsible for the quality of its drugs, and must do what is necessary to identify and address all impurities, in particular genotoxic probable human carcinogens**. (Jun Du 5/28/21 Dep. Tr., 250:4-17 (ZHP Ex. 29); Min Li 4/20/21 Dep. Tr., 268:8-11 (ZHP Ex. 11)).

68. Admitted that the USP monograph did not contain an explicit specification for nitrosamines, but denied that no specifications existed since the USP monograph explicitly required that in the event of a manufacturing process change analytical methods and specifications were required to be established to detect and identify impurities (ZHP Ex. 19, p. 4; ZHP Ex. 20, p. 9), moreover the

ICH, EMEA, and FDA regulatory guidances all characterized n-nitroso compounds as part of the cohort-of-concern of extremely toxic substances that were required to be identified and prevented (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13, 329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143)), and [redacted] (Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (ZHP Ex. 46) (discussing ZHP Ex. 122)). In addition, the FDA rejected ZHP's excuses for not identifying or preventing the nitrosamine contamination. (ZHP01344159-62 (ZHP Ex. 28)).

69. Denied (See Footnote 6), and the ICH, EMEA, and FDA regulatory guidances all characterized n-nitroso compounds as part of the cohort-of-concern of extremely toxic substances that were required to be identified and prevented (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13, 329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143)), [redacted] (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13, 329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143); Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (ZHP Ex. 46) (discussing ZHP Ex. 122)). In addition, the FDA rejected ZHP's excuses for not identifying or preventing the nitrosamine contamination. (ZHP01344159-62

(ZHP Ex. 28)). The scientific literature clearly stated the methods to test for nitrosamines, for example according to the IARC 1978 Monograph, "[i]t has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields NDMA," and "[t]he principal techniques employed for the analysis of volatile N-nitrosamines [including NDMA] have been described in a recent publication… high- and low-resolution mass spectrometry are discussed, since use of mass spectrometry as a confirmatory technique is particularly important." (Min Li 4/21/21 Dep. Tr. 458:13-465:11 (ZHP Ex. 22)).

70. Denied (See Footnote 6), and the threshold ZHP claims it relied on was not applicable to cohort-of-concern substances including NDMA and NDEA (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13, 329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143)), the USP required all impurities to be identified when a change was made to the manufacturing process (ZHP Ex. 19, p. 4; ZHP Ex. 20, p. 9), and the FDA rejected ZHP's excuses and explanations for why it failed to disclose the NDMA in its valsartan. (ZHP01344159-62 (ZHP Ex. 28)).

71. Denied to the extent of reliance on expert reports and testimony (see Footnote 6). Admitted that this statement was made but it is presented incompletely and without proper context, as ZHP should have known to look for nitrosamines and

to identify them. (ZHP01344159-62 (ZHP Ex. 28); Dr. Hecht 7/6/2021 R. 1, 6-27 (ZHP Ex. 139); Dr. Hecht 10/31/2022 Suppl. R. 1-11 (ZHP Ex. 144)).

72. Denied to the extent of reliance on expert reports and testimony (see Footnote 6). Denied that this is an accurate statement, although there was not a specific specification for NDMA or NDEA in valsartan, that is because their formation was never contemplated or approved, and the USP monograph explicitly required that in the event of a manufacturing process change analytical methods and specifications were required to be established to detect and identify impurities. (ZHP Ex. 19, p. 4; ZHP Ex. 20, p. 9).

73. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and the USP monograph explicitly required that in the event of a manufacturing process change analytical methods and specifications were required to be established to detect and identify impurities (ZHP Ex. 19, p. 4; ZHP Ex. 20, p. 9), moreover the ICH, EMEA, and FDA regulatory guidances all characterized n-nitroso compounds as part of the cohort-of-concern of extremely toxic substances that were required to be identified and prevented (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13, 329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143)), and [redacted]

(Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (ZHP Ex. 46) (discussing ZHP Ex. 122)).

In addition, the FDA rejected ZHP's excuses for not identifying or preventing the nitrosamine contamination. (ZHP01344159-62 (ZHP Ex. 28)).

74. Admitted, specific to valsartan, however denied that this is a defense or viable excuse for the failure to identify and detect genotoxic impurities as to drug products in general including valsartan, as the FDA made clear that a manufacturer was required to detect and identify all nitrosamine impurities in general, the ICH, EMEA, and FDA regulatory guidances all characterized n-nitroso compounds as part of the cohort-of-concern of extremely toxic substances that were required to be identified and prevented (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13, 329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143))), and [redacted] (Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (ZHP Ex. 46) (discussing ZHP Ex. 122)). In addition, the FDA rejected ZHP's excuses for not identifying or preventing the nitrosamine contamination. (ZHP01344159-62 (ZHP Ex. 28)).

75. Admitted, specific to valsartan, however this is because no level of NDMA or NDEA was permitted before that time, the ICH, EMEA, and FDA regulatory guidances all characterized n-nitroso compounds as part of the cohort-of-concern of extremely toxic substances that were required to be identified and prevented (Min Li 4/21/21 Dep. Tr. 296:23-298:4, 308:14-309:2, 321:21-323:13,

329:18-330:5, 339:5-340:20; 381:1-390:20, 467:14-470:7 (ZHP Ex. 22) (discussing ZHP Exs. 141-143)), and [redacted] (Peng Dong 3/29/21 Dep. Tr., 33:9-34:10 (ZHP Ex. 46) (discussing ZHP Ex. 122)). In addition, the FDA rejected ZHP's excuses for not identifying or preventing the nitrosamine contamination. (ZHP01344159-62 (ZHP Ex. 28)).

76. Admitted, however denied that this supports the position that USP did not require identification and prevention of genotoxic impurities as the USP monograph explicitly required that in the event of a manufacturing process change analytical methods and specifications were required to be established to detect and identify impurities which encompassed nitrosamines, and also provided that any substance known to be toxic shall not listed under the other impurities section thereby requiring specific identification. (ZHP Ex. 19, p. 4; ZHP Ex. 20, p. 9). USP defines toxic impurities as follows:

> Toxic impurities have significant undesirable biological activity, even as minor components, and require individual identification and quantification by specific tests. These impurities may arise out of the synthesis, preparation, or degradation of compendial articles. Based on validation data, individualized tests and specifications are selected. These feature comparison to a Reference Standard of the impurity, if available. It is incumbent on the manufacturer to provide data that would support the classification of such impurities as toxic impurities.

(ZHP Ex. 167, p. 2). Genotoxic impurities, such as NDMA and NDEA, can damage and mutate genes/DNA and then cause cancer. (ZHP Ex. 103, p. 17; ZHP Ex. 102, p. 12; ZHP Ex. 154, p. 8; ZHP Ex. 141, p. 2, 10; ZHP Ex. 142, p. 6). According to the USP's definition, they are a paradigmatic example of toxic impurities that drug manufacturers are required to identify, quantify, and then include in their specifications. (ZHP Ex. 167, p. 2).

77. Admitted that this was stated by the FDA, however denied that this is a complete statement of the FDA's position, but rather is a misleading cherry-picked part of what the FDA has stated. See Paragraph 61 for more details.

78. Admitted that the quoted statements were included, however the FDA never found that the NDMA and NDEA contamination was acceptable, and found that the ZHP API was adulterated due to cGMP violations that directly damaged the quality of the valsartan, and all of the contaminated VCD's were recalled. (ZHP01344159-62 (ZHP Ex. 28); ZHP00061080 (ZHP Ex. 27); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119)).

79. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied because the term "intended purpose of providing effective hypertension treatment" is undefined, and misleading and incomplete, since the intended purpose was first of all to be the FDA approved, compendium compliant, with proper quality and purity, safe, valsartan, and instead the valsartan was

adulterated with unapproved genotoxic probable human carcinogens, presenting "an unacceptable carcinogenic risk to the intended patient population," and requiring a recall of the valsartan once the contamination was disclosed. (ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119)). ZHP's own witness confirmed that the FDA determined that the levels of NDMA in the valsartan [redacted] from a health standpoint. (Min Li 4/21/21 Dep. Tr., 478:20-479:19 (ZHP Ex. 33)). Nor do the Defendants present evidence that the valsartan effectively controlled the high blood pressure of every person who utilized the VCDs.

80. Denied to the extent of reliance on expert reports and testimony (see Footnote 6). Admitted that this was stated, in part. Dr. Najafi, a chemist, testified that he didn't know if VCDs containing NDMA or NDEA still lowered blood pressure and deferred to a toxicologist or physician. (Dr. Najafi 2/3/2022 Dep. Tr., 193:4-19) (ZHP Ex. 165)).

81. Denied as to the characterization of the reasons for the FDA's statement, including the alleged efficacy and important medical benefits of the VCDs. Admitted that the FDA recommended that people promptly replace their VCDs with one or more of the numerous alternative medications prescribed by their physicians before stopping use of the contaminated pills because of the immediate risks to their health from completely ceasing the use of medication to control high

blood pressure, which was deemed a more immediate risk than the longer term increased risk of cancer. This was a decision between two bad choices that was created by Defendants' widespread marketing of the contaminated valsartan. Defendants also omit the FDA's clear direction in the same document that (1) "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests," (2) "As we seek the removal of certain drug products today, our drug shortages team is also working hard to ensure patients' therapeutic needs are met in the United States with an adequate supply of unaffected medications," (3) "Patients should also contact their health care professional (the pharmacist who dispensed the medication or doctor who prescribed the medication) if their medicine is included in this recall to discuss their treatment, which may include another valsartan product not affected by this recall or an alternative treatment option." (Defs.' Ex. 1). Taken as a whole, the FDA's statement is clear that the FDA agreed that Defendants' VCDs needed to be recalled due to their contamination with a probable human carcinogen, but due to ZHP's domination of the market with its contaminated API, the FDA, pharmacists, and doctors needed to monitor patients and assist them with replacing their contaminated medication with safe alternatives based on what was available to them in their specific circumstances at the time.

82. Admitted that these statements were part of what the FDA set forth in its statement, including the focus on the availability of safe replacements and different treatment options. Admitted that the FDA recommended that people promptly replace their VCDs with one or more of the numerous alternative medications prescribed by their physicians before stopping use of the contaminated pills because of the immediate risks to their health from completely ceasing the use of medication to control high blood pressure, which was deemed a more immediate risk than the longer term increased risk of cancer. This was a decision between two bad choices that was created by Defendants' widespread marketing of the contaminated valsartan. The FDA's statement is even titled, in part, "FDA Statement on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve **ongoing safety issue**." (Defs.' Ex. 74 (emphasis added)). The FDA then described the contamination as "**not acceptable**" and an "**unnecessary risk to patients**" that should be prevented in the future, and described the contamination as "alarming to patients who expect their products to be free from these types of impurities." (*Id.*). The FDA was adamant that it needed to "ensure affected medications are removed from the U.S. supply chain" "to protect patients from unnecessary exposure to these impurities." (*Id.*). In light of the contamination and the public's justified alarm, the FDA created a list of "nitrosamine-free ARBs" to provide the public with some level of assurance that it

could take those drugs without incurring the risk created by Defendants in this case. (*Id.*). Defendants' failure to manufacture unadulterated ARBs, including VCDs, "led to shortages" that the FDA had to "mitigate" and "prevent" "as often as possible." (*Id.*). As a result the FDA had to "keep working with manufacturers to eliminate these impurities from the drug supply, but [also] recognize that we also need to ensure patients who need ARBs have access now." (*Id.*). Nevertheless, the FDA "reiterated steps [Manufacturers] should take to ensure these impurities are not present in any ARB in the future." (*Id.*). The FDA even advised that "Health care practitioners should familiarize themselves with alternative medicines that can be used to treat hypertension, heart failure or renal disease in case of shortages." (*Id.*).

83. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and Defendants made numerous such representations and warranties, including on their labels, websites, and in the DMFs and ANDAs, in all making clear that they were marketing FDA approved, compendium compliant valsartan. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-134, 145-154.5; Torrent SOMF ¶ 32–38, 40–41. *See* Teva SOMF ¶¶ 37-38; *see also, e.g.*, TEVA-MDL2875-00367183 (Teva-100) [redacted] TEVA-MDL2875-00203906 (Teva-101) (same). **Of note, the DMF regarding the new zinc chloride manufacturing process falsely warranted that "there was not any high potency genotoxic group, such as N-nitroso**

compounds," in the valsartan API, when in fact there was NDMA in the valsartan. (Min Li 4/21/21 Dep. Tr., 492:24-493:20 (ZHP Ex. 22); HUAHAI-US00007899 (ZHP Ex. 74)). The DMF for the TEA with sodium nitrite quenching process also contained this affirmative misrepresentation. (PRINSTON00080119 (ZHP Ex. 75)).

84. Denied that the TPP Plaintiffs did not receive any representations from the TPP trial Defendants. Numerous representations were made that were relied on, including on their labels, websites, and in the DMFs and ANDAs, and via USP and the Orange Book, in all making clear that they were marketing FDA approved, compendium compliant valsartan. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-134, 145-154.5; Torrent SOMF ¶ 32–38, 40–41). *See* Teva SOMF ¶¶ 37-38; *see also, e.g.*, TEVA-MDL2875-00367183 (Teva-100) ([redacted] TEVA-MDL2875-00203906 (Teva-101) (same). The cited testimony fails to address the facts in a thorough or directly relevant way and does not negate the fact that the key representations were made and relied on by the TPP's. See Paragraph 108 below for further details.

85. Denied that the TPP Plaintiffs did not receive any representations from the TPP trial Defendants. Numerous representations were made that were relied on, including on their labels, websites, and in the DMFs and ANDAs, and via USP and

the Orange Book, in all making clear that they were marketing FDA approved, compendium compliant valsartan. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-134, 145-154.5; Torrent SOMF ¶ 32–38, 40–41). *See* Teva SOMF ¶¶ 37-38; *see also, e.g.*, TEVA-MDL2875-00367183 (Teva-100) ([redacted]); TEVA-MDL2875-00203906 (Teva-101) (same). The cited testimony fails to address the facts in a thorough or directly relevant way and does not negate the fact that the key representations were made and relied on by the TPP's. See Paragraph 108 below for further details.

86. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied, as there was no specification for NDMA and NDEA in the FDA approved, compendium compliant, DMF compliant valsartan, or the ANDA, because there was no amount of NDMA or NDEA permitted. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-163.2).

87. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), Admitted in substance.

88. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted in part that these are some of the requirements for the ANDA. However, an ANDA must also include a "full description of the drug substance [or API] including its physical and chemical characteristics and stability;

…the process controls used during manufacture and packaging; and **the specifications necessary to ensure the** identity, strength, **quality**, and **purity** of the drug substance," and a "list of all components used in the manufacture of the drug product [or FD] (regardless of whether they appear in the drug product) and a statement of the composition of the drug product; the specifications for each component; … a description of the manufacturing and packaging procedures and in-process controls for the drug product; **the specifications necessary to ensure the** identity, strength, **quality**, **purity**, potency, and bioavailability of the drug product." 21 C.F.R. § 314.50(d) (applied by reference to ANDAs in 21 C.F.R. § 314.94(a) (emphasis added)).

89. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that these are some of the requirements for pharmaceutical equivalence, as well as the same quality and purity.

90. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that these are some of the requirements for bioequivalence. Plaintiffs' claims are not related to whether the VCDs were or were not bioequivalent. *See* 21 C.F.R. § 314.3 (defining bioequivalence as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes

available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.").

91. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that an AB rating in the Orange Book encompasses therapeutic equivalence and bioequivalence, which includes the same quality and purity as the RLD, and that the valsartan was manufactured in compliance with cGMPs. (Pls.' Affirmative ZHP SOMF ¶ 147-148).

92. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied that an AB rating in the Orange Book encompasses therapeutic equivalence and bioequivalence, which includes the same quality and purity as the RLD, and that the valsartan was manufactured in compliance with cGMPs, thus the NDMA and NDEA contamination due to directly applicable cGMP violations rendered the valsartan adulterated, and negated the ability to market or describe the valsartan as FDA approved, USP compliant, or AB rated. (Pls.' Affirmative ZHP SOMF ¶ 147-148; ZHP01344159-62 (ZHP Ex. 28)). Dr. Najafi testified that while it is not required for a generic drug to match every impurity of the branded drug, "they do require that the impurity is to be determined safe." (Dr. Najafi 2/3/2022 Dep. Tr., 193:4-19) (ZHP Ex. 165)). Furthermore, Dr. Najafi's report clearly states, "Defendants' valsartan containing products were not the generic, pharmaceutical, therapeutic and chemically equivalent form of Diovan or

Exforge because they contained NDMA and NDEA." (Dr. Najafi 10/31/2022 R. 29 (ZHP Ex. 166)).

93. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as the terms are undefined and overbroad, and the failure to specify the type or level of impurities makes it impossible to admit this statement, as the change in the impurity profile of the Defendants' valsartan rendered the valsartan adulterated, not the FDA approved or compendium compliant formulation, and required a recall and import ban, and in fact USP requires that all impurities be identified and properly addressed when there is a change to the manufacturing process as occurred here. (ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119); ZHP00061080 (ZHP Ex. 27); Pls.' Affirmative ZHP SOMF ¶ 52).

94. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied, as the terms including "clinical efficacy," are not defined, and the NDMA, a genotoxic, probable human carcinogen, that is a cohort-of-concern substance, rendered the valsartan adulterated, not the FDA approved or compendial compliant formulation. *See, e.g.*, Teva SOMF at ¶ 8-23, 29, 96-101.

95. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that adulteration is statutorily defined, admitted that adulteration can be identified by the FDA, as occurred here where the FDA

determined that ZHP's API was adulterated, and that Torrent's VCD's were adulterated, due to the contamination with genotoxic probable human carcinogens caused by cGMP violations, and denied as to the legal conclusion that this is a regulatory determination that only the FDA can make, as set forth in Plaintiffs' Brief in Support of Motions for Partial Summary Judgment (in addition to this being a legal conclusion, not a statement of fact). (ZHP01344159-62 (ZHP Ex. 28); TORRENT-MDL2875-00072716 (ZHP Ex. 145); Nigh Cert. Ex. 10.).

96. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that the FDA issued a Warning Letter to ZHP on or about November 29, 2018 determining that the valsartan API, which had already been recalled and was no longer being sold, was adulterated, and the FDA also notified Torrent on or about August 17, 2018, that its VCD's containing the ZHP contaminated adulterated valsartan API was adulterated, denied as to when the FDA first made such a finding as Defendants have presented no evidence proving that stated fact. (ZHP01344159-62 (ZHP Ex. 28); TORRENT-MDL2875-00072716 (ZHP Ex. 145); Nigh Cert. Ex. 10).

97. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied that no applicable regulatory action was taken, as the ZHP API was found to be adulterated and required to be recalled, as any pill containing that API contaminated with a genotoxic probable human carcinogen presented an

unacceptable carcinogenic risk. *See* (ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119); Teva SOMF ¶ 1, 6-7 ([redacted]); Teva SOMF ¶ 96-101 ([redacted]). Admitted in part that the FDA did not issue a warning letter to Teva about Teva's VCDs or send communications to Teva that its ANDAs were no longer AB-rated, but denied that any of this means Teva's VCDs were not adulterated, contaminated, misbranded, or made in a non-cGMP compliant manner because, inter alia, Teva was ultimately responsible for the valsartan API in its VCDs, and that API was present in every one of Teva's VCDs, and was adulterated. *See* Teva SOMF ¶¶ 8-22, 26-29. The FDA did not need to issue a warning letter or communication to Teva about the AB-rating of its VCDs because Teva stopped selling VCDs. *See, e.g.*, Osmian Dep. 107:18-115:19 (Teva-112); Teva-119 [redacted].

98. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that the labeling was the FDA approved labeling representing that the valsartan was the FDA approved, compendial compliant formulation of valsartan, denied that the formulation was as approved and the

specifications were met as contamination with the genotoxic probable human carcinogens NDMA and NDEA was never approved as part of the specifications. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-134, 145-163.2).

99. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as to the legal conclusions as to FDA action, denied that the VCDs met the specifications, as contamination with the genotoxic probable human carcinogens NDMA and NDEA was never approved as part of the specifications. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-163.2).

100. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as to the legal conclusions as to FDA action, denied that the VCDs met the specifications, as contamination with the genotoxic probable human carcinogens NDMA and NDEA was never approved as part of the specifications. *See, e.g.,* TEVA-MDL2875-00057086 [redacted] Admitted in part that the FDA did not issue a warning letter to Teva about Teva's VCDs or send communications to Teva that its ANDAs were no longer AB-rated, but denied that any of this means Teva's VCDs were not adulterated, contaminated, misbranded, or made in a non-cGMP compliant manner because, inter alia, Teva was ultimately responsible for the valsartan API in its VCDs, and that API was present in every one of Teva's VCDs and was adulterated. *See* Teva SOMF ¶¶ 8-22, 26-29. The FDA did not need to

issue a warning letter or communication to Teva about the AB-rating of its VCDs because Teva stopped selling VCDs. *See, e.g.*, Osmian Dep. 107:18-115:19 (Teva-112); Teva-119 ([redacted]); ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119).

101. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as to the legal conclusions as to FDA action, denied that the VCDs met the specifications, as contamination with the genotoxic probable human carcinogens NDMA and NDEA was never approved as part of the specifications. Deny that Torrent never received notice of the FDA's determination that its VCDs were adulterated. (Nigh. Cert. Ex. 10.) [redacted] (*Id.*) [redacted] (TORRENT-MDL2875-00515246; ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119); TORRENT-MDL2875-00072716 (ZHP Ex. 145)).

102. Admitted that MSP is not a TPP and has never been a plan sponsor. MSP, however, has acquired via assignment rights from TPPs and plan sponsors.

103. Admitted. [redacted] MSP Ex. 1, Lopez Dep. 134:22-138:8.

104. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied, as the terms such as "intricate web" are undefined and this statement appears to be an opinion.

105. Admitted in part. [redacted] Denied that *all* of MSP's assignors do so.

106. Denied as phrased. [redacted]

107. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied. Defendants' statement is unsupported by any potentially admissible evidence.

108. Admitted that the Defendants' statement accurately reflects the deponents' testimony. However, denied that there were no express warranties. The questions that defendants posed in the deposition were intentionally ambiguous and misleading, and phrased as legal conclusions that aren't properly asked to lay witnesses, and Defendants failed to ask questions intended to identify whether there were any representations and facts that would support an express warranty. [redacted]

[redacted] MSP Ex. 5, MSP Ex. 6, MSP Ex. 7; MSP Ex. 16.

109. Admitted in part that PBMs were involved in the Summacare and Emblem transactions in this case. Denied as to other unidentified entities that were "possibly involved." Defendants' statement is also unsupported by potentially admissible evidence.

110. Admitted in part. Admitted that PBMs generally have a role in paying for medication but deny the statements as to the timing of the payments, which are wholly unsupported by the documents that Defendants cite.

111. Admitted in part. Admitted that some self-funded plans use TPAs, but deny the statements as to the timing of the payments, which are wholly unsupported by the documents and testimony that Defendants cite.

112. Denied. The mere fact that Emblem's corporate representative did not know whether pre-suit notice was sent, does not mean that pre-suit notice was not sent by SummaCare, MSP, or by or on behalf of, "any of the TPP Class members," as defendants assert. Notice was sent. MSP Ex. 8; MSP Ex. 9; MSP Ex. 10; MSP Ex. 11; MSP Ex. 12; Teva Suppl. SOMF ¶ 110.

113. Admitted in part that a formulary is a "continually updated list of medications approved for reimbursement." But denied that the only consideration in formulary placement is "to encourage members to use the most cost-effective generic drugs available," as defendants assert. That statement is wholly unsupported by the documents and testimony that Defendants cite.

114. Admitted.

115. Admitted in part that P&T committees can be associated with a PBM or TPP. Denied as to the vague and undefined statement that "most" P&T

committees are associated with PBMs. That statement is also wholly unsupported by the documents that Defendants cite.

116. Admitted.

117. Admitted in part that TPPs use formularies and work with the PBM to determine, among other things, whether to cover specific drugs or class of drugs and how to share costs between patients and the TPPs. Denied that "one SummaCare formulary contained 50 alternatives to treatment with a VCD." That statement is not supported by the document that Defendants cite.

118. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted in part that the stated tests were included, however the stated facts are incomplete since the USP also required that additional tests be established and used in the event of a manufacturing process change, and that was not done by any defendant. (Pls.' Affirmative ZHP SOMF ¶ 52).

119. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted in part that P&T Committees use the Orange Book to determine therapeutic equivalence rating for generic drugs. Denied that "TPPs typically do not use the Orange Book at all" and that "TPPs do not rely on the Orange Book for decisions to reimburse members' claims." *See* MSP Ex. 13, Panagos Oct. 31, 2022 Rep. ¶ 99. Additionally, Professor Rena Conti, Ph.D.'s following opinions,

support that TPPs relied on Defendants' compliance with applicable standards, obligations, and regulations in determining which drugs to reimburse:

> Pharmaceutical manufacturers' compliance with cGMPs in manufacturing prescription drugs and assurances that prescription drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess on the FDA approved label as required by law and applicable regulations provides the foundation upon which prescription drugs are sold and purchased in the United States. If a prescription drug is available for sale in the United States, patients and third-party payers rely on the manufacturer's assurance that the drug has the safety, identity, purity, potency, and quality it purports to have, as required by law and applicable regulations.
>
> * * *
>
> Moreover, manufacturer compliance with these laws and regulations assuring the safety and quality of prescription drugs sold in the United States market is foundational to the payment for prescription drugs by third-party payers. Third-party payers make prescription drug coverage and purchasing decisions based on manufacturers' compliance with all applicable safety and quality laws and regulations governing the sale of FDA-approved prescription drugs. In this matter, the end-payors relied on the Defendants to manufacture and sell prescription drugs that comply with all laws and regulations so that each at-issue Valsartan product had the safety, identity, purity, potency, and quality that its label represented it possessed.40 Similarly, patients who filled prescriptions for at-issue Valsartan products had no choice but to rely on the manufacturers' assurance of safety, efficacy and compliance with all laws and regulations. This is due to the asymmetrical nature of knowledge regarding pharmaceutical safety and quality which I discuss below.

* * *

> In addition, third-party payers continuously assess whether and which prescription drug treatments might provide their members benefit and value to treat medical conditions and symptoms. The assurance of safety and quality by the manufacturers of prescription drugs is foundational to third-party payers' decision making. In other words, in the United States prescription drug market, insurers do not monitor drug manufacturers' compliance with laws and regulations related to safety and quality; that is not their job. Instead, they presume that drug manufacturers are in compliance with all applicable laws and regulations related to safety and quality, that the drugs are not adulterated or misbranded and that the FDA and other regulatory agencies have monitored the manufacturers' efforts to ensure compliance, otherwise they would not be placed into the stream of commerce. There is no insurer demand for non-safety and quality compliant, adulterated, and misbranded drugs.

(Conti 11/10/21 Rep. ¶ 21, 37, 40 (ZHP Ex. 155)). Dr. Panagos' following opinions, none of which were excluded by the Court in its January 5, 2024 ruling, support that TPPs relied on Defendants' compliance with applicable standards, obligations, and regulations and on Defendants' compliance with information in the Orange Book when creating their formularies and determining which drugs to reimburse:

1. Use of generic drugs that have been deemed bioequivalent by the FDA does not require a full new round of review or approval by a P&T Committee, because the TPPs and P&T Committees expressly rely upon the manufacturers' compliance with all applicable standards, obligations, and regulations. (Dr. Panagos 10/31/22 Rep. ¶ 78 (ZHP Ex. 156)).

2. It is industry practice that a drug must be safe in order to gain approval by the FDA and a listing in the Orange Book is an important source which by design is relied on throughout the pharmaceutical industry. (*Id.* at ¶ 85).

3. TPPs, PBMs, and P&T Committees rely on the FDA approval as the indicator that the medication may be considered for formulary placement and plan coverage/reimbursement. (Summary of Opinion VI).

4. The Orange Book lists the FDA approved generics of the original brands. The pharmaceutical industry, including TPPs, are meant to be able, by design, to rely on the information in the Orange Book such that these FDA approved generics can be put on a prescription drug formulary and/or plan coverage for reimbursement. (Summary of Opinion VII).

5. P&T committees and TPPs rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan. (Dr. Panagos 10/31/22 Rep. ¶ 99).

120. Denied to the extent of reliance on expert reports and testimony (see Footnote 6). *See* MSP Ex. 12, Panagos Oct. 31, 2022 Rep. ¶ 99-101.

121. Denied to the extent of reliance on expert reports and testimony (see Footnote 6). The Court precluded the purported expert testimony on which Defendants base their assertion.

122. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that P&T committees rely on multiple sources of information to develop formularies, including those listed.

123. Denied. Defendants' statement is wholly unsupported by the deposition testimony to which Defendants purport to cite. Additionally, as shown above in Plaintiffs' response to statement 108, there were a multitude of representations and assurances that Defendants didn't ask about in the deposition.

124. Admitted in part that Emblem's corporate representative testified that she was unaware whether anyone at Emblem ever viewed Defendants' websites or VCD-related literature or ever communicated with Defendants about the medications. Denied that the corporate representative was unaware of any formulary changes. [redacted] MSP Ex. 14, M. Finn Dep. Tr. 146:14-147:8; 152:17-25. Additionally, as shown above in Plaintiffs' response to statement 108, there were a multitude of representations and assurances that Defendants didn't ask about in the deposition.

125. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as the terminology suggesting there was no diminished benefit is undefined, and misleading and incomplete, since the intended purpose was first of all to be the FDA approved, compendium compliant, with proper quality and purity, safe, valsartan, and instead the valsartan was adulterated with unapproved genotoxic probable human carcinogens, presenting "an unacceptable carcinogenic risk to the intended patient population," and requiring a recall of the valsartan once the contamination was disclosed. (ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119)).

126. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and admitted that the VCDs were represented and labeled as FDA-

approved and legal to market, purchase, and sell, permitting the transactions to be made, denied that the VCDs were the FDA-approved, legal to market, purchase, and sell formulation because they were contaminated with genotoxic probable human carcinogens that rendered the VCD's adulterated and the contaminated VCD's presented an unacceptable carcinogenic risk to the intended patient population. (Pls.' Affirmative ZHP SOMF ¶ 52, 126-134, 145-163.2; ZHP01344159-62 (ZHP Ex. 28); SOLCO00024231 (ZHP Ex. 118); SOLCO00024226 (ZHP Ex. 119)).

127. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied, as there is ample evidence that the TPP class members incurred direct, out-of-pocket costs associated with the recall. For example, [redacted]. MSP Ex. 15, T. Mrakovich Dep. Tr. 183:16-23; MSP Ex. 16; MSP Ex. 7.

128. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as stated. Dr. Conti has repeatedly opined that an adulterated drug has no economic value *See, e.g.*, Conti 2/10/22 Dep. (Teva-120) at 114:20-116:3, 204:11-24. Further, the annotated snippet of testimony that Defendants cite

related to a question about medical marijuana, and Dr. Conti's full answer (uncited by Defendants) frames her answer consistently with her prior testimony. *See* Conti 7/13/23 Dep. at 26:2-18.

129. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as stated. Dr. Conti has repeatedly opined that therapeutic benefit is a separate issue from economic value, and that adulterated drugs have no economic value regardless of their efficacy. *See, e.g.*, Conti 2/10/22 Dep. (Teva-120) at 114:20-116:3, 204:11-24. 145:-12-146:24. Further, the annotated snippet of testimony that Defendants cite relates to products that *have* a demand curve, which Dr. Conti exhaustively opines is not the case for adulterated drugs. *See id.*

130. Denied to the extent of reliance on expert reports and testimony (see Footnote 6), and denied as stated. Dr. Stiroh's opinions on alternative medications in a counterfactual world are irrelevant and unreliable opinion. Taken to its logical end, if "the cost of alternative products" were a viable defense in consumer warranty or similar cases, there would be no viable case (individual or class), because Defendants would be able to claim that the Plaintiffs would have purchased something else. The reason courts do not even entertain these types of irrelevant arguments is because damages are losses attributable to a wrong, and what Plaintiffs might have done in a completely counterfactual world has no bearing on the loss that was traceable to the breach of warranty or other wrongful conduct.

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Respectfully submitted,

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